

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING)
PHARMACY, INC. PRODUCTS LIABILITY)
LITIGATION)

MDL No. 2419
Dkt. No 1:13-md-2419 (RWZ)

THIS DOCUMENT RELATES TO:)

Leave to file granted at Dkt. 1222

All Cases)

**TENNESSEE CLINIC DEFENDANTS’
SUPPLEMENTAL SUMMARY BRIEF OF POSITION ON DISCOVERY ISSUES**

These Tennessee clinics and physicians – Saint Thomas Outpatient Neurosurgical Center, LLC; Howell Allen Clinic, a Professional Corporation; John W. Culclasure, MD; Debra V. Schamberg, RN; Specialty Surgery Center, Crossville, PLLC; Kenneth R. Lister, MD; Kenneth Lister, MD, PC; and Donald E. Jones, MD (collectively referred to herein as the “Tennessee Clinic Defendants”) come now and file this *Supplemental Summary Brief of Position on Discovery Issues*.

1. Introduction

a. Purpose of this brief

Pursuant to the Court’s ruling at Dkt. 1222, the Tennessee Clinic Defendants file this brief to (1) summarize their position on how discovery should be conducted in the 100+ Tennessee cases pending in the MDL and (2) present their proposal for a discovery plan (with deadlines) and bellwether framework in this MDL.¹

¹ This brief is filed on behalf of all Tennessee Clinic Defendants. However, the proposed discovery plan attached as exhibit 13 addresses only St. Thomas-related cases. The Tennessee Clinic Defendants anticipate that a similar discovery plan with similar provisions and timeframes would be entered for SSC-related cases (and, potentially, for each individual clinic with a substantial number of cases). The SSC-

The Tennessee Clinic Defendants intend this brief to synthesize all their previous pleadings on discovery issues into one summary document presenting their position and proposal.

b. Who we are

In September 2012, clinicians at Vanderbilt in Nashville diagnosed a patient with fungal meningitis. In short order, involved clinicians and the Tennessee Department of Health traced the illness to contaminated methylprednisolone acetate (“MPA”) compounded by New England Compounding Center (“NECC”).² As additional cases were diagnosed, the investigation continued, and investigators determined that NECC had shipped vials from the contaminated batches to three Tennessee clinics – Saint Thomas Outpatient Neurosurgical Clinic (Nashville, TN), Specialty Surgery Center (Crossville, TN), and PCA Pain Care (Oak Ridge, TN).

A flood of lawsuits against NECC followed. It soon became apparent that NECC and its insurance could not cover the potential liability for its contamination of the medication. NECC’s bankruptcy was inevitable; the petition was filed in December 2012. Predictably, plaintiffs’ attorneys shifted focus to other avenues of recovery. Because Tennessee has a relatively short one-year statute of limitations for health care liability actions, the three Tennessee clinics moved to the crosshairs. Scores of lawsuits naming the Tennessee Clinic Defendants followed.

related discovery plan would include a smaller number of trial candidate cases and bellwether trial cases given the smaller overall universe of SSC-related cases. This is discussed in more detail below.

² For background, see Kainer, *et al.*, *Fungal Infections Associated with Contaminated Methylprednisolone in Tennessee*, *ENG J MED* 2012; 367: 2194-2203 (December 6, 2012).

The parties filing this brief – the Tennessee Clinic Defendants³ – are:

STOPNC, et al.⁴:

- Saint Thomas Outpatient Neurosurgical Center, LLC (“STOPNC”) – an ambulatory surgery center in Nashville, Tennessee where contaminated NECC MPA was administered to plaintiffs
- Howell Allen Clinic (“Howell Allen”) – a group of neurosurgeons and one-half owner of STOPNC, and also the employer of John Culclasure, MD (“Dr. Culclasure”) and Debra Schamberg, RN (“Ms. Schamberg”)
- Dr. Culclasure – anesthesiologist and the medical director of STOPNC; administered MPA to plaintiffs at STOPNC and also participated in the decision to buy MPA from NECC
- Ms. Schamberg – nurse and the facility director of STOPNC; participated in the decision to buy MPA from NECC

SSC, et al.:

- Specialty Surgery Center (“SSC”) – an ambulatory surgery center in Crossville, Tennessee, where NECC MPA was administered to plaintiffs
- Kenneth Lister, MD (“Dr. Lister”) – an anesthesiologist; administered NECC MPA to plaintiffs at SSC and participated in the decision to buy MPA from NECC
- Kenneth Lister, MD, PC (“Dr. Lister’s Practice”) – Dr. Lister’s practice entity

Dr. Jones:

- Donald Jones, MD (“Dr. Jones”) – an anesthesiologist at PCA Pain Care in Oak Ridge, Tennessee, where NECC MPA was administered to plaintiffs.

c. Summary of position of Tennessee Clinic Defendants on discovery

The Tennessee Clinic Defendants’ position on discovery issues is simple:

1. Discovery should be phased into (1) common discovery and (2) the bellwether selection process (which includes selection of bellwether cases

³ The cases against the Tennessee Clinic Defendants can be divided into three baskets: (1) 88 cases (117 patients) against STOPNC, et al.; (2) 24 against SSC, et al., and (3) two against Dr. Jones. (Dr. Jones administered MPA at PCA Pain Care.)

⁴ In this brief, for brevity’s sake, STOPNC, Howell Allen, Dr. Culclasure, and Ms. Schamberg shall sometimes be referred to as “STOPNC, et al.” And, SSC, Dr. Lister, and Dr. Lister’s Practice shall sometimes be referred to as “SSC, et al.”

and case-specific discovery).⁵ Consistent with this approach, the Tennessee Clinic Defendants propose an order governing common discovery⁶ and a separate order setting the bellwether framework.⁷

2. Deadlines should be put in place to ensure the steady but reasonable pace of common discovery, culminating in a time for the parties to consider a Tennessee-specific mediation. Should mediation not be pursued or fail, the parties will continue into selection of bellwether trial pool cases and case-specific discovery in those cases, with further narrowing to the bellwether trial cases. Additionally, at the conclusion of common discovery, the parties and Court should consider whether (and when) the cases should be remanded to district court(s) in Tennessee.
3. Certain provisions, as discussed herein, must be included in the discovery plan to ensure a mutual, fair exchange of information. This includes lifting the discovery stay as to the Affiliated Defendants and NECC to allow the Tennessee Clinic Defendants discovery of information relevant to (1) the defense of the claims against them, (2) potential comparative fault claims, and (3) potential third-party claims.
4. A framework for bellwether selection can be put in place at this point, but it is premature to set specific deadlines beyond common discovery.
5. The differences in facts from clinic to clinic and differences in applicable law from state to state make outcomes in cases against one clinic in one state less predictive of outcomes in cases against other clinics and in other states. Thus, discovery plans and bellwether frameworks should be clinic-specific. The Tennessee Clinic Defendants propose a discovery plan and bellwether framework herein for use in St. Thomas-related cases. A separate but similar plan and framework should be put in place for SSC-related cases.

2. Background relevant to this brief

The timeline below does not purport to cover the entire procedural history of this MDL⁸ but instead presents a chronological look at the timeline entries most relevant to the instant parties' position on discovery:⁹

⁵ There should also be, at some point, an analysis of whether bellwether cases are even appropriate.

⁶ Exhibit 13 to this brief.

⁷ Exhibit 14 to this brief.

⁸ This MDL has, at present, 1,257 filings in the electronic docket.

⁹ In the timeline, italics are used when quoting from letters or comments by the Court.

2013

- January 29 First case against Tennessee health care providers¹⁰ filed in Tennessee state court; three more follow
- April 30 / May 28 STOPNC and Howell Allen respond to over 200 interrogatories and requests for production in the state court litigation and ~60 requests for admission, turning over hundreds of pages of documents; later, STOPNC and Howell Allen, after lengthy meet and confers and a court hearing, serve two rounds of supplemental discovery responses, constituting hundreds more pages of documents
- June 11 On the eve of depositions of the Defendants in the state court cases, the Plaintiffs voluntarily dismiss all lawsuits without prejudice
- June 17 The PSC serves non-party subpoenas on the Tennessee Clinics (and dozens of other health care providers) in the MDL; four different versions of the same subpoenas follow
- September 12 The first lawsuits against the Tennessee Clinic Defendants in federal court are filed, and shortly thereafter are transferred to the MDL; scores more follow
- September 17 Now parties to the MDL, the Tennessee Clinic Defendants make first formal request for access to the 40,000 documents that NECC produced to the Plaintiffs; that request is refused on this occasion and on numerous subsequent occasions
- September 26, 27 The Saint Thomas Entities¹¹ file a motion to reconsider Case Management Order 7, which established discovery and bellwether selection deadlines, arguing that the order was unworkable now that numerous other defendants had been added to the fray;¹² STOPNC, *et al.* join in the Saint Thomas Entities' motion to reconsider CMO 7 a day later¹³
- October 7 The PSC opposes the request to have the Court revisit CMO 7¹⁴

¹⁰ *Wayne A. Reed, individually and as husband and next of kin of decedent, Diana Reed, v. Saint Thomas Outpatient Neurosurgical Center, LLC, Howell Allen Clinic, a Professional Corporation, Saint Thomas Network, Saint Thomas Health, and St. Thomas Hospital*, No. 13C-417, Davidson County Circuit Court.

¹¹ For simplicity, this brief will utilize "Saint Thomas Entities" to refer to the various St. Thomas Hospital-related entities named as defendants in Tennessee suits. The Saint Thomas Entities are separate defendants from STOPNC, *et al.*, represented by separate counsel.

¹² Dkt. 457.

¹³ Dkt. 459.

¹⁴ Dkt. 478.

- October 8 At the monthly status conference, the Court directs the parties to meet and confer on the discovery motion, ruling that the motion, for the time being, will remain pending¹⁵
- October 9 Despite the Court's directive, the PSC serves 400+ discovery requests on STOPNC, *et al.*,¹⁶ requests production of 50,000 emails that had been segregated, and demands initial disclosures from STOPNC, *et al.*; the PSC also announces their intent to take depositions of parties in 60 days¹⁷
- October 10 The Tennessee Clinic Defendants respond in writing, proposing a reasonable and measured plan for discovery in place of the then-pending discovery requests and subpoena: *"I propose we have a discussion designed to agree on a date by which the plaintiffs with suits against STOPNC and Howell Allen will produce their initial disclosures, and we will serve our initial disclosures by the same deadline, consistent with FRCP 26. We will begin working on our discovery responses in anticipation of receipt of your initial disclosures"*¹⁸
- October 16 The PSC responds, refuses to withdraw its subpoenas in light of sending written discovery, and demands initial disclosures immediately¹⁹
- October 18 Tennessee Clinic Defendants respond, request an in-person meet and confer, and propose the following plan:
- Mutual exchange of initial disclosures by November 8, followed by exchange of common written discovery
 - Plaintiffs will send LR 35.1 information by November 8²⁰
 - Plaintiffs will provide 20 search terms for search of emails
 - Limits of 200 RFAs and 35 ROGs

¹⁵ See Clerk's Notes from October 8, 2013, status conference (Dkt. 519).

¹⁶ These 400+ discovery requests are largely duplicative of the requests answered in the state court litigation and made in the subpoena, in many instances simply "cut and pasted" from one document to the next. The PSC made no discernible effort to avoid sending duplicative requests, and, as noted later in this timeline, actually took the position that it would be easier for the Tennessee Clinic Defendants to just answer discovery requests repeatedly, no matter how many times asked.

¹⁷ This letter is attached as exhibit 1 to this brief.

¹⁸ This letter is attached as exhibit 2 to this brief.

¹⁹ This letter is attached as exhibit 3 to this brief.

²⁰ As this Court knows, LR 35.1 requires disclosure of basic medical information as part of the initial exchange of information. This process was supplanted later by the Plaintiff Profile Form.

- Depositions will be deferred until written discovery is complete and global motions to dismiss are resolved²¹

October 28

The PSC files its motion to lift the stay of discovery as to the Affiliated Defendants²²

November 7

At the monthly status conference, the Court extends the time to further brief the pending motion to reconsider CMO 7 [Dkt. 457, 459]

November 11

After several meet and confer sessions between the PSC and the Tennessee Clinic Defendants designed to (1) streamline the duplicative discovery sent by the PSC and (2) develop a reasonable, balanced discovery plan, the PSC responds in writing, eviscerating any progress that had been made in the meet and confer process:

"You have requested the PSC identify the differences in the recent discovery served and the discovery served in the [state court] case. After initially reviewing these differences, we realized that the discovery we recently served took into consideration many of the issues brought up in the meet and confer process in state court, and accordingly, the easiest way forward is for you to simply answer all discovery responses [sic] posed on October 9, 2013, regardless of whether a given request is the exact same request served in the state court litigation."^{23 24}

The PSC also proposes:

- No search protocol for ESI is needed; the defendants would simply search the 92 search terms proposed
- *"We suggest that you de-dupe [the 50,000] emails, review all of them, and produce those that are responsive and non-privileged."*

²¹ This letter is attached as exhibit 4 to this brief.

²² Dkt. 534.

²³ (emphasis added). This letter is attached as exhibit 5 to this brief.

²⁴ The absurdity of the PSC's position in this letter – that answering numerous repetitive requests is the "easiest" way to proceed – was apparently not appreciated by the PSC, but that statement is illustrative of the overall difficulty in getting a reasonable and balanced plan put in place.

- A 14-day extension to respond to the 400+ requests, respond to the subpoena, and review the 50,000 emails, all around the Thanksgiving holiday²⁵

November 25

The parties, at an apparent impasse in negotiating a plan to conduct discovery, file motions with the Court stating their positions regarding discovery:

Dkt. 591: PSC's proposal

Dkt. 592: Saint Thomas Entities' proposal

Dkt. 598: Tennessee Clinic Defendants' proposal

As part of the proposals at Dkt. 592/598, the Saint Thomas Entities and the Tennessee Clinic Defendants formally request that the Court stay discovery of them until a discovery plan is put in place

At 598-2, the Tennessee Clinic Defendants proposed a discovery plan for common discovery with the following provisions:

- Exchange common initial disclosures by December 18
- Master common written discovery exchanged by December 20, with limits of 200 RFAs, 40 ROGs, and 60 RFP
- Respond to common written discovery by February 20
- Motions to Compel on written discovery issues by March 20
- Depositions of Tennessee Clinic Defendants will begin 45 days after any disputes regarding written discovery are resolved
- The limits in the FRCP on deposition duration and number of depositions control, and the PSC will have one questioning attorney during depositions
- After common discovery, cases will be selected to constitute the bellwether trial pool, and case-specific discovery of cases in this bellwether trial pool will follow

December 10

The PSC files its opposition to the Tennessee Clinic Defendants' proposal²⁶

²⁵ Notably, during this period (and still), the Tennessee Clinic Defendants have held their set of common written discovery to the PSC based on the Court's repeated directive to the parties that a discovery plan needed to be in place before the parties launch into discovery.

²⁶ Dkt. 617.

December 13

At the monthly status conference, in discussing the filed proposals on discovery, Judge Saylor says at least five times that he wishes the litigation to proceed by resolving motions to dismiss, followed by an organized and planned discovery period. For instance:

- *“I do need to, as in any case, resolve motions to dismiss, get discovery underway to the extent appropriate and so on. I think the time has come to get organized along those lines **beginning with the resolution of motions to dismiss, creating a framework for that so that they can be decided and we can move on.** What I hope to accomplish in some reasonable short term is exactly that, to know what the universe of short complaints are and **to permit defendants who so intend to have their 12(b)(6) motions or other preliminary motions resolved, either they win or they lose, and we go on from there.**”²⁷*
- *“12(b)(6), again, we’re going to basically follow the Rules of Civil Procedure. Right upfront, **if you’re a defendant, you have a right to file a motion that says this does not state a claim upon [which] relief can be granted.** I may deny them all, I don’t know what I am going to do, but you have that right, and I’m going to give them [that] right....”²⁸*
- *“**I’m not sure we can truly avoid 26(f) conferences** at least, I mean, we have defendants who are individual physicians, and we have defendants who are multi-national corporations, and there are a lot of different types of defendants here, and they may be in very different positions, and **it has to be sensible and tailored as makes sense under the circumstances.**”^{29 30}*

December 16

The Tennessee Clinic Defendants, at the request of the PSC, formally “adopt” their state court discovery responses into MDL³¹

December 20

The PSC threatens a motion for contempt over the pending subpoenas³²

²⁷ Hr’g Tr. 16:10-23 (Dec. 13, 2013, Status Conference).

²⁸ *Id.* at 29:7-13.

²⁹ *Id.* at 78:16-22.

³⁰ Compare this to the position of the PSC in its November 6, 2011, letter (exhibit 3) that Rule 26(f) conferences in this litigation would be “unheard of.”

³¹ This letter is attached as exhibit 6 to this brief.

³² This letter is attached as exhibit 7 to this brief.

December 23

Judge Saylor formally vacates the deadlines related to bellwether selection in CMO 7³³

December 30

The Tennessee Clinic Defendants write again in an attempt to heed Judge Saylor's directive and institute a reasonable discovery plan:

- *"I do not think we are going to be able to resolve our disagreements on the way written discovery should be conducted without ruling(s) on [the motion to stay discovery pending entry of a discovery plan and the motion for entry of a discovery plan]. However, I write one last time in an attempt to reach an agreement on how to proceed while these motions remain pending."*
- The Tennessee Clinic Defendants, with the letter, served formal responses and objections to the discovery sent October 9, 2013, and the subpoenas, formally stating their objection that, consistent with Judge Saylor's directive and the FRCP, a discovery plan should be put in place before launching into written discovery
- *"[W]e are still willing to agree to the written discovery protocol we proposed with Dkt. 598, which I thought was very reasonable. However, at this point, if we plan to travel under the limits in the FRCP and the local rules, as the PSC has proposed, we are limited in all forms of discovery and cannot serve any discovery until initial disclosures are made. I propose, again, that we mutually exchange initial disclosures (a 'common' PSC set for STOPNC cases and SSC cases and 'common' sets for STOPNC, et al. and SSC/Lister) in short order. We would then proceed to answer the 'common' discovery that is outstanding to us, and we will serve the 'common' set of written discovery on the PSC that we have been withholding pending entry of a plan setting reasonable limits on written discovery. I also think our limits of 200 RFAs/40 ROGs/60 RFPs are reasonable."*

"Otherwise, I suppose we can wait for Judge Boal to work through these issues and enter a discovery protocol, which will take time, and we will probably end up with something that looks like what we proposed at Dkt. 598. Under our proposal with Dkt. 598, you would already have our initial disclosures, and complete responses to the written discovery

³³ Dkt. 721.

(to the extent not covered by the initial disclosures) would be forthcoming after the holidays.”

“Please take another look at our proposed written discovery plan with Dkt. 598. Without it, we would both launch into discovery with no limits or protocols except the FRCP and local rules, which do not contemplate this complicated and unique litigation. Let’s see if we can put a reasonable agreed protocol in place while the motion to stay written discovery and motion for discovery plan are still pending.”³⁴

2014

January 10

At the monthly status conference, the Court again instructs the parties to establish a discovery plan before launching into discovery:

- ***“[B]efore you take discovery from the other side, there needs to be some kind of plan in place or order that directs and sets deadlines and so on....”***³⁵
- *“Part of what St. Thomas raised was also a motion to stay discovery pending a discovery plan. I do want to take this up at some point today. What I said about having a discovery plan for the affiliated defendants obviously applies to the unaffiliated defendants as well, some degree of planning and coordination needs to be done here. You know, even in a simple case, we have a scheduling conference where the parties have to meet and confer. That needs to be discussed as well. We don’t necessarily need to resolve it today, but that issue does need to be resolved....”*³⁶
- *“Certainly as to the St. Thomas entities that you represent,³⁷ I’m going to direct the parties to meet and confer on this discovery plan. I may spin some of this off to Magistrate Judge Boal, I may keep it, I don’t know, but certainly it makes sense for you all to get together and talk about what you think makes sense to see if you can agree, and we’ll handle it that way.”*³⁸

³⁴ This letter is attached as exhibit 8 to this brief.

³⁵ Hr’g Tr. 49:23-25 (Jan. 10, 2014, Status Conference).

³⁶ *Id.* at 40:24-35; 41:1-8, 17-22.

³⁷ The Court was speaking to counsel for the Saint Thomas Entities at this point. Although STOPNC and St. Thomas are separate legal entities, the two have been lumped together at various hearings.

³⁸ Hr’g Tr. 48:5-12 (Jan. 10, 2014, Status Conference).

- *“I was thinking of a discovery protocol, which, in other words, discovery from plaintiffs [is] going to be dealt with in the short term, the fact sheets and so forth. Discovery from your client’s perspective.”³⁹ I want you to meet and confer to talk about a possible plan.”⁴⁰*

January 31

Despite the Court’s charge that the parties should meet and confer and instruction that a discovery plan needs to be in place before launching into discovery, the PSC files a motion for entry of a pre-trial scheduling order, asking the Court to fast-track the cases from written discovery to trial in 15 months with no allowance for discovery of NECC or the Affiliated Defendants⁴¹

February 5

The Tennessee Clinic Defendants respond to the PSC’s entirely unworkable proposal in writing by letter and filing with the Court⁴²:

- *“The [PSC] proposed deadlines may seem plausibly achievable in the abstract, but, when considered in the context of the amount of work required at each step, it is readily apparent that the deadlines simply are not manageable...We prefer to plan on the front-end, setting out a reasonable and manageable progression of this litigation specific to the Tennessee defendants rather than unworkable deadlines, in the hope of avoiding unnecessary expenditure of time and resources.”*
- The letter points out the numerous problems with the PSC’s proposal and again proposes a more balanced, steady schedule for common discovery.⁴³ *“We should, at this point, concentrate on establishing a realistic plan for conducting common discovery, which will efficiently usher us into case-specific discovery and bellwether selection.”*
- The proposal includes:
 - Provisions for discovery of Affiliated Defendants
 - Time for review of Plaintiff Profile Forms
 - Time to allow for review of 40,000 NECC documents
 - Mutual exchange of initial disclosures
 - Mutual exchange of common written discovery
 - Reasonable expert disclosure deadlines

³⁹ Again, the Court was specifically addressing counsel for the Saint Thomas Entities.

⁴⁰ Hr’g Tr. 48:17-22 (Jan. 10, 2014, Status Conference).

⁴¹ Dkt. 837.

⁴² Dkt. 858, and letter attached as exhibit 9 to this brief.

⁴³ See 858-3 for the Tennessee Clinic Defendants’ proposed discovery plan filed February 5, 2014.

- Time to explore Tennessee-specific mediation
- A bellwether selection framework
- Tennessee Clinic Defendants again request to meet and confer, per the Court's desire, on their proposed plan

March 3 The Saint Thomas Entities file their position on discovery,⁴⁴ asking the Court to deny the PSC's motion for entry of its pre-trial scheduling order for many of the same reasons set out in the Tennessee Clinic Defendants' February 5 filing

March 3 UniFirst files its position on discovery,⁴⁵ asking the Court to, in essence, table discovery while motions to dismiss are argued and decided and other parties are added to the litigation

March 11 The PSC responds on the discovery issues, arguing for its "fast-track" scheduling order⁴⁶

March 28 The Tennessee Clinic Defendants join in the PSC's October 2013 motion to lift the discovery stay as to the Affiliated Defendants⁴⁷

April 17 The PSC writes the Tennessee Clinic Defendants, still ignoring the three separate discovery plans proposed by the Tennessee Clinic Defendants:

- *"The PSC maintains that discovery is fully open and the parties should proceed with full written discovery posthaste."*
- Demands *"immediate[]"* supplementation of all requests and threatens to file motions to compel and for sanctions
- Demands that counsel review the 50,000 segregated emails and *"dispense with electronic searches of this material"*
- Demands a response by April 21 (essentially within one business day)⁴⁸

April 25 The Tennessee Clinic Defendants make one final attempt at a reasonable, collegial approach to the PSC's demands, writing a lengthy letter setting out their position⁴⁹.

⁴⁴ Dkt. 964.

⁴⁵ Dkt. 965.

⁴⁶ Dkt. 1001.

⁴⁷ Dkt. 1041.

⁴⁸ This letter is attached as exhibit 10 to this brief.

⁴⁹ This letter is attached as exhibit 11 to this brief.

- *“First, let me make clear our position, a position that has not changed since October 2013. We believe:*
 1. *The ongoing motion to dismiss process should resolve at the outset of this litigation.*
 2. *Before launching into common written discovery, which we consider to include both (1) ‘common’ initial disclosures from both sides (the PSC and our clients) and (2) a master set of ‘common’ written discovery from both sides⁵⁰, a ‘discovery plan’ should be agreed upon or entered by the Court.*
 3. *Such a discovery plan would include provisions addressing, at a minimum, the following:*
 - a. *Reasonable timeframes for reciprocal production of initial disclosures.*
 - b. *Reasonable limits on the numbers of interrogatories, requests for production, and requests for admission.*
 - c. *Reasonable deadlines for the service of and answering of the initial set of common written discovery from the PSC to the Tennessee Clinic Defendants and from the Tennessee Clinic Defendants to the PSC.*
 - d. *Now, given the entry of the standard plaintiff profile form (‘PPF’), reasonable deadlines for completion of the PPF, raising of objections to the completed PPFs, and supplementation of the incomplete PPFs.⁵¹”*
- *“At no time have we said we do not believe you are entitled to written discovery from our clients or to take their depositions. We are ready and willing to engage in common written discovery so long as a reasonable plan is put in place. We may disagree on what constitutes a reasonable discovery plan. That is what the meet and confer process is designed for. But, our position has simply been that a plan*

⁵⁰ “I understand that you consider your requests served in October 2013 to be the ‘common’ set from the PSC. We have withheld ours pending entry of a discovery plan.” [footnote in original 4/25/14 letter, exhibit 11].

⁵¹ “Such a plan would also include reasonable deadlines for disclosure of and depositions of common experts and for common dispositive motion practice not done during this initial motion to dismiss phase. But, the portion of the discovery plan addressing written discovery is the focus of this letter.” [footnote in original 4/25/14 letter, exhibit 11].

should be in place before launching into costly and time-consuming written discovery.”

- *“We have operated consistent with the directives of Judge Saylor and the policy behind the federal rules in our attempts to set a plan with reasonable parameters for discovery. We wrote on October 10, October 18, and December 30, addressing discovery issues. Each time, we proposed a reasonable plan to establish a timetable for reciprocal initial disclosures, deadlines for reciprocal written common discovery, and limits on the numbers of interrogatories, RFPs, and RFAs. We filed what I sincerely believe are reasonable proposals at 598-2 and 858-3 to govern common discovery. Some variation of these proposals must be entered before launching into common written discovery.”*
- *“You contend...that the Court denied the motions to stay discovery and cite Dkt. 783. I looked at Dkt. 783. The Order at Dkt. 783 addresses St. Thomas’s motion at Dkt. 594 (its motion for amendment of the protective order at Dkt. 397). The Order at Dkt. 783 that you contend denied the motions to stay does not even address them. Thus, our motions to stay discovery pending entry of a discovery plan are still pending, and they remain pending with the directive to us that we meet and confer to establish such a plan.”*
- The letter concluded with the Tennessee Defendants’ last-ditch effort to compromise on these issues and another request to meet and confer on the discovery plan per the Court’s direction:

“Third, let me suggest where we go from here. I will not reargue the points made in the original motions to stay and the briefing at Dkt. 858. I will also not reargue the points we have made in opposition to the PSC’s bellwether proposal. I will only propose what I believe to be a reasonable compromise on the common written discovery issues.”

“I propose that the PSC reconsider Section I of our filing at 858-3. Section I comprises a discovery plan for written discovery, i.e., (1) a timeframe for reciprocal initial disclosures, (2) reasonable limits on the number of interrogatories, RFPs, and RFAs, (3) deadlines for completion and supplementation of the PPFs, and (4) a reasonable timeframe for exchange

of written common discovery requests. I enclose another copy of 858-3. Provision 'I' can be amended to allow for the Trustee's agreement that the PSC can allow us access to the NECC documents."

"I propose that we meet and confer on the discovery plan, using 858-3's Section I as a starting point, as directed by Judge Saylor in mid-January. In the several months since the directive to meet and confer on the discovery plan, the parties have reached agreement on the ESI protocol and concluded the meet/confer and argument process on the deposition protocol.⁵² I propose we do the same on the written discovery plan."

"In the interim, while we negotiate the written discovery portion of the discovery plan contemplated by Judge Saylor, we will continue the process of gathering documents and information from our clients to send initial disclosures and answer the discovery sent in October, and Plaintiffs can begin the process of completing the PPFs."

"Please let me know your thoughts. I am available to confer in person or by phone on these issues April 30 (afternoon), May 1 (anytime), or May 5 (anytime)."

* * * * *

This request went unanswered and was, in essence, the conclusion of the dialogue on discovery issues. Judge Zobel referred the issues to this honorable Court, for hearing on July 17, 2014.

3. Where we are now and where we are going

The above rehashes how we arrived at this point. Now, we must decide how to proceed. Put simply, it is imperative that we put in place a reasonable and measured discovery plan to move this litigation through common discovery, into the selection of

⁵² "In addition, much of the last 90 days has been spent on a motion to dismiss briefing." [footnote in original 4/25/14 letter, exhibit 11].

bellwether pool cases for case-specific discovery phase, and then through case-specific discovery in a subset of cases for trial as bellwethers.

a. What we have in place and what we need

The parties have briefed and argued, and the Court has entered, a form Plaintiff Profile Form, which will serve as the vehicle by which individual plaintiffs will provide information to the Defendants.

The parties have agreed upon a protocol for the exchange of ESI.

The parties have briefed and argued the contents of a deposition protocol to this Court. When the Court rules, the parties will have a deposition protocol in place to govern the taking of depositions.

The parties now need (1) a discovery plan governing common discovery and (2) a framework for bellwether cases that governs the selection bellwethers, case-specific discovery, and bellwether trials.

b. Guiding principles

i. Utility of a discovery plan

The letter and policy of the FRCP and the local rules, the directives of Judge Saylor early in this litigation, the *Manual for Complex Litigation, Fourth*, and common sense all support the imposition of an overall discovery plan to govern common discovery.

First, FRCP 26(f) specifically requires that the parties confer and develop, with the Court's input if necessary, a discovery plan.⁵³ "[T]he purpose of pretrial discovery is to 'make trial less a game of blind man's bluff and more a fair contest with the basic

⁵³ FED. R. CIV. P. 26(f).

issues and facts disclosed to the fullest practicable extent.”⁵⁴ FRCP 26(f) specifically delineates what must be addressed in the discovery plan:

- Initial disclosures under FRCP 26(a)
- The subjects of discovery, when discovery will be had, and whether it should be phased or focused on certain issues
- ESI
- Issues regarding claims of privilege or work-product protection
- Whether the standard FRCP or local rules should be modified for the case.

The comments to FRCP 26 note its intent: “The purpose of discovery is to provide a mechanism for making relevant information available to the litigants.”⁵⁵ “Mutual knowledge” of the facts is essential to proper litigation.⁵⁶ FRCP 26(f) discovery conferences and plans are intended to encourage efficient and economical discovery.⁵⁷

The Massachusetts District Court Local Rules echo the importance of early overall management of discovery by requiring that the parties confer and develop a plan for discovery.⁵⁸

Second, as noted above, the Court never indicated it wished to dispense with the planning procedures of the FRCP and local rules. In fact, the Court indicated just the opposite, repeatedly directing the parties to meet and confer on a discovery plan before launching into costly discovery.

Third, the *Manual for Complex Litigation* amplifies the importance of an overall discovery plan in complex litigation. “A discovery plan should facilitate the orderly and

⁵⁴ *Ojo v. Eldin Medic*, No. 11-cv-210-JL (D. N.H. 2012).

⁵⁵ FED. R. CIV. P. 26(f) (cmts., 1983 amendment).

⁵⁶ FED. R. CIV. P. 26(f) (cmts., 1983 amendment) (citing *Hickman v. Taylor*, 329 US 495, 507 (1947)).

⁵⁷ FED. R. CIV. P. 26(f) (cmts., 1993 amendment).

⁵⁸ LR 16.1(b).

cost-effective acquisition of relevant information and materials and the prompt resolution of discovery disputes.”⁵⁹ “The plan should reflect the circumstances of the litigation, and its development and implementation must be a collaborative effort with counsel.”⁶⁰ The *Manual* devotes 12 pages to the implementation of an overall discovery plan before beginning written discovery.⁶¹

Lastly, common sense dictates that, before engaging in costly and time-consuming discovery, the parties should have an overall plan in place. Without a discovery plan in place ahead of service of discovery in this MDL, the parties have expended countless hours arguing about initial disclosures, duplication in requests sent, and time limits for responding. These are the exact issues the overall discovery framework would resolve on the front-end.

ii. Bellwether selection process

The Tennessee Clinic Defendants premise their proposed discovery plan and bellwether framework on Judge Eldon E. Fallon’s⁶² guidance for managing MDLs.⁶³

The Tennessee Clinic Defendants anticipate that the parties will use the already developed Plaintiff Profile Form to obtain basic information on a plaintiff and to assess whether a plaintiff is appropriate for inclusion in the initial bellwether candidate pool. Each side will then nominate eight cases apiece for the bellwether trial candidate pool.⁶⁴

⁵⁹ *Manual for Complex Litigation, Fourth*, 51.

⁶⁰ *Manual for Complex Litigation, Fourth*, 51.

⁶¹ *Manual for Complex Litigation, Fourth*, 51-62.

⁶² During his tenure as a federal district court judge for the Eastern District of Louisiana, Judge Fallon has presided (or is presiding) over the Propulsid MDL, MDL No. 1355, the Vioxx MDL, MDL No. 1657, and the Chinese Drywall MDL, MDL No. 2407. He has written extensively on how this type of litigation should be most effectively managed.

⁶³ Fallon, *et al.*, *Bellwether Trials in Multidistrict Litigation*, TULANE LAW REV., Vol. 82, p. 2223 (2008) (hereinafter “Fallon, [page number]”).

⁶⁴ Depending on which defendants are left in the litigation, this number and process may need modification.

Once selected for the bellwether trial candidate pool, the parties will conduct individual case-specific discovery of the cases in the bellwether candidate pool. After individual case discovery, the parties will propose four bellwether trial cases from the bellwether candidate pool. After bellwether trial cases are selected, they will be tried.

This process is consistent with that described in Judge Fallon's article, *Bellwether Trials in Multidistrict Litigation*:

1. First, catalogue the entire universe of cases, and divide them into distinct, easily ascertainable categories of cases.
2. Second, select a manageable pool of cases that reflects the various categories of cases and contains cases that are amenable to trial in the MDL. Proceed with case-specific discovery in these cases.
3. Third, the court and attorneys collaborate near the end of case-specific discovery to select a pre-determined number of individual cases within the sample and set them for trial.⁶⁵

As Judge Fallon explained, without representative bellwethers, "the transferee court and the attorneys risk trying an anomalous case, thereby wasting substantial amounts of both time and money."⁶⁶ The Plaintiff Profile Form phase will be used in assisting the parties from Judge Fallon's step one to step two – identifying a pool of bellwether trial candidates.

At the same time, the common discovery phase will begin the long road of discovery necessary to prepare these cases for trial. This overall discovery process must have a sufficient exchange of meaningful information prior to bellwether trial case selection to ensure the selection of representative cases and to ensure fair trial of these representative cases. The Tennessee Clinic Defendants' proposals fairly accomplish these goals.

⁶⁵ Fallon, 2343.

⁶⁶ Fallon, 2344.

c. PSC's position

The PSC's position is fairly represented in the above recitation of the history leading to this brief. It is characterized by the following:

- A consistent unwillingness to engage in mutual exchange of initial disclosures and common discovery
- A refusal to withdraw or modify discovery that the PSC itself admits is largely duplicative of discovery already served
- Extremely aggressive deadlines.

This is not how discovery should work.

d. Proposal

i. Discovery plans and bellwether frameworks should be clinic-specific

The Court should probably put in place an overall bellwether selection framework in order to set appropriate deadlines in a common discovery plan. The Tennessee Clinic Defendants respectfully submit that the bellwether process and common discovery plan should be clinic-specific. Otherwise, significant problems will arise as clinic-defendants from states with multi-year statutes of limitations are added to the MDL in the coming months (or years), after the expiration of various deadlines for common discovery and/or bellwether selection.⁶⁷

Utilizing a clinic-specific bellwether process will also ensure that the bellwether process serves its predictive function. There is no variation in the facts from the defense

⁶⁷ By adopting a clinic-specific process, the Court can adopt a plug and play approach for common discovery. When a new clinic is added as a defendant, the Court can use the structure in the common discovery plan used for the Tennessee Clinic Defendants but set deadlines for completion of discovery to accommodate the late arrival of the new clinic.

side above the clinic level.⁶⁸ The predictive value of a bellwether case will be the same for the non-clinic defendants, regardless of which case is chosen as a bellwether.⁶⁹

For the clinic defendants, on the other hand, a bellwether trial involving a different clinic, particularly a clinic from another state, will have little or no predictive value. The only real factual variation from the defense side is the relationship between the clinics and NECC, specifically the due diligence undertaken by the clinic prior to purchasing from NECC. Whether a New Jersey jury finds that a New Jersey clinic did or did not undertake adequate due diligence under New Jersey law provides no real predictive value for a Tennessee clinic governed by Tennessee law.

The most logical means of avoiding these problems is to adopt a clinic-specific common discovery plan and bellwether selection process.

ii. Tenets of the Tennessee Clinic Defendants' proposal

The Tennessee Clinic Defendants respectfully submit that the following *must* be included in the discovery plan in order to ensure the orderly progression of this case toward bellwether trials:

1. The discovery plan must be phased into (1) common discovery and then (2) bellwether selection and case-specific discovery. At this point, setting specific deadlines for case-specific discovery and deadlines for pretrial activities is premature. There are too many unknowns – *e.g.*, the status of NECC, the status of the various National and Affiliated Defendants, the resolution of numerous legal issues in the pending dispositive motions, the status of defendants coming into the suits presently or in the near future and potentially settling or being dismissed, the ease or difficulty with which certain discovery will occur – to plan these cases all the way through trial.
2. The discovery plan must allow for the mutual exchange of initial disclosures between the PSC and the Defendants. Initial disclosures are the most efficient

⁶⁸ I.e., the evidence likely to be presented at trial for NECC, the Affiliated Defendants, and the National Defendants should be the same irrespective of the state law, clinic, or plaintiff involved in a given case.

⁶⁹ The only possible exception is the application of state law to the claims against for NECC, the Affiliated and National Defendants, but a clinic-specific process accounts for differences in state law.

way to exchange basic information at the outset of discovery. The FRCP, the local rules, and the *Manual for Complex Litigation* all encourage their use. This litigation should be no different.

3. Adequate time must be included for review of the 40,000 NECC documents that are presently in the repository. This review should start very soon, once access is arranged, but it will take time.
4. The Tennessee Clinic Defendants must be afforded access to the data⁷⁰ obtained by the PSC during its 2012 inspection of NECC. Despite the order governing the inspection contemplating access to this information by all defendants,⁷¹ the PSC has refused to turn most of the information over.⁷²
5. The discovery plan should include reasonable limits on interrogatories, requests for production, and requests for admission.
6. The discovery plan must allow for discovery of the Affiliated Defendants and of NECC. Discovery of these entities is important for the development of comparative fault and third-party claims by these Defendants. Additionally, they hold discoverable information important to the defense of the claims against the Tennessee Clinic Defendants.⁷³
7. At the conclusion of common discovery, when reciprocal discovery has occurred sufficient to more fully evaluate factual issues, liability issues, and potential exposure, time should be allotted to explore a Tennessee-specific mediation. Also, once common discovery of NECC and the National and Affiliated Defendants has completed, it may be the proper time to remand the cases to Tennessee's district court for case-specific discovery and trials. Thus, at the conclusion of common discovery, if mediation fails or is not pursued, the parties should confer and consider whether remand to Tennessee's district court is appropriate.⁷⁴

⁷⁰ Within the last week, the PSC has given the Tennessee Clinic Defendants access to the video from the 2012 inspection. But, the PSC refuses to provide access to the crucial remaining data from the 2012 inspection.

⁷¹ Order Setting Protocol for Onsite Inspection and Testing of New England Compounding Center, Framingham, MA. *Erkan v. NECC*, No. 1:12-cv-12052-RWZ, Dkt. 126, adopted in MDL by MDL Order No. 6, MDL Dkt. 209.

⁷² See letter exchange on inspection documents, attached as exhibit 12 to this brief.

⁷³ For instance, the Plaintiffs allege that the Tennessee Clinic Defendants conspired with NECC to circumvent regulatory law. The contact of the Tennessee Clinic Defendants with NECC was through Medical Sales Management, an Affiliated Defendant. The Tennessee Clinic Defendants need to discover documents and testimony from Medical Sales Management to defend the conspiracy claim.

⁷⁴ Attached as exhibit 15 is a diagram illustrating the conceptual discovery/bellwether framework set forth in detail in the Tennessee Clinic Defendants' proposed orders attached as exhibits 13 and 14. Exhibit 15 is intended to give the Court an overview of the Tennessee Clinic Defendants' proposals in broad strokes.

8. The plan must include reasonable deadlines. The PSC has a habit in this litigation of pushing for deadlines, not meeting them, and requiring extension.⁷⁵ The deadlines in the PSC's latest proposal were, frankly, ridiculous. For example:

- The proposal allowed the Defendants 15 days after receipt of the Plaintiff Profile Forms to notify the Plaintiffs of any material deficiencies. Fifteen days is barely enough time to read all the forms, much less obtain records for each Plaintiff, cross-check the records with the forms to ensure completeness, and formally notify the Plaintiffs of all deficiencies.
- The PSC's proposal requires identification of trial cases within 60 days of receiving the Plaintiff Profile Forms. At the 60-day mark, the Defendants will likely not even have received all the relevant records on the Plaintiffs, and certainly will not have digested the records sufficient to make meaningful selections.
- From the conclusion of expert disclosures, the PSC proposes 40 days to depose experts. The parties will disclose at least 20 experts, and probably many more. Forty days to depose all experts in the case is absurd.
- After case-specific discovery ends, the parties are allotted seven days to make trial picks. Transcripts on depositions will not even have returned. A week for this important task is laughable.
- Overall, the PSC's proposal contemplates discovery in eight bellwether cases and common discovery all happening simultaneously, and all to be concluded in about nine months. A single, simple car accident case often cannot be readied in that time.

iii. Tennessee Clinic Defendants' proposal for discovery plan and bellwether framework

The Tennessee Clinic Defendants attach as exhibit 13 to this brief their proposed discovery plan to govern the first phase of discovery – common discovery.⁷⁶

⁷⁵ See, e.g., Motion for Extension of Time to File Mediation Order [Dkt. 363]; Request for Extensions to File Master Complaint and Short Form Complaint [Dkt. 395]; Motion to Extend Deadlines in Previous CMO and to Revise CMO [Dkt. 421]; Motion to Extend Deadlines Set Forth in Mediation Program [Dkt. 487]; Motion for Extension of Time to File Master Complaint as to Affiliated Defendants [Dkt. 540]; Motion to Extend Deadline for Filing List of Subpoena Recipients Named as Defendants [Dkt. 574]; Motion for Extension of Time to Respond to Traveler's Motion to Quash [Dkt. 737]; Motion to Extend Deadline for Filing Master Complaint Against Affiliated Defendants [Dkt. 741]; Motion for Extension of Deadline to Respond to Trustee's Renewed Motion to Transfer [Dkt. 760]; Motion for Additional Extension of Time to Respond to Traveler's Motion to Quash [Dkt. 765].

⁷⁶ The proposed discovery plan attached as exhibit 13 governs only the St. Thomas-related cases, but the proposed framework and deadlines should work equally well for the SSC-related cases.

The Tennessee Clinic Defendants attach as exhibit 14 to this brief their proposed order governing the second phase of discovery – case-specific discovery and bellwether selection.⁷⁷ This proposed order has no specific deadlines entered and no specific provisions for case-specific discovery. Those deadlines should be set once sufficient progress has been made in common discovery to allow for assignment of reasonably attainable deadlines for the second phase of discovery.

4. Conclusion

If the PSC had accepted any of the three discovery plans that the Tennessee Clinic Defendants proposed since October 2013, initial disclosures would have been exchanged, written discovery answered, and depositions likely scheduled or underway. However, the PSC has maintained throughout that little or no planning is necessary and that this litigation can proceed unchecked at breakneck speed to trials. Judge Saylor repeatedly warned against that and ordered development of a discovery plan, consistent with all available authority and scholarly guidance.

The Tennessee Clinic Defendants' proposed common discovery plan and bellwether framework are fair and reasonable protocols to move this litigation forward. The Tennessee Clinic Defendants urge the Court to enter them or enter a substantially similar plan.

⁷⁷ Again, the proposed bellwether selection framework governs only St. Thomas-related cases. The overall framework should work equally well for SSC-related cases, with the number of cases halved at each stage of the selection process to account for the fewer number of cases against SSC (24 suits vs. 88 suits). Each side will select four cases for inclusion in the "Initial Trial Pool," and two cases will be chosen as the "First Bellwether Trials."

Respectfully submitted,

/s/ Chris J. Tardio

C.J. Gideon, Jr.⁷⁸

Chris J. Tardio⁷⁸

Alan S. Bean⁷⁹

Matthew H. Cline⁷⁸

315 Deaderick Street, Suite

Nashville, TN 37238

Ph: (615) 254-0400

Fax: (515) 254-0459

chris@gideoncooper.com

***Attorneys for the Tennessee Clinic
Defendants***

CERTIFICATE OF SERVICE

I certify that this document filed through the CM/ECF system will be served electronically to the registered participants identified on the Notice of Electronic Filing and copies will be e-mailed or mailed via regular U.S. mail to those participants identified as unregistered this 10th day of July, 2014.

/s/ Chris J. Tardio

Chris J. Tardio

⁷⁸ Admitted pursuant to MDL Order No. 1.

⁷⁹ Admitted *pro hac vice*.